Food and Drug Administration, HHS

and 56.2 milligrams of vitamin E (68 I.U.) (as d-alpha tocopheryl acid succinate) or 0.548 milligram of sodium selenite (equivalent to .25 milligram of selenium and 14 milligrams of vitamin E (17 I.U.) (as d-alpha tocopheryl acid succinate.)

- (b) Sponsor. See No. 000061 in §510.600(c) of this chapter.
- (c) Conditions of use. (1) The drug is intended for use as an aid in alleviating and controlling inflammation, pain, and lameness associated with certain arthropathies in dogs.
- (2) The capsules are administered orally with the larger capsules administered at a dosage level of 1 capsule per 20 pounds of body weight to a maximum of 5 capsules with the dosage repeated at 3 day intervals until a satisfactory therapeutic response is observed. A maintenance dosage is then administered consisting of 1 capsule per 40 pounds of body weight, with a minimum of 1 capsule per 40 pounds of body weight, with a minimum of 1 capsule, given every 3 days, or 7 days, or longer, as required to maintain improvement or an asymptomatic condition. For dogs under 20 pounds of body weight, the small capsules are administered orally at a dosage level of 1 per 5 pounds of body weight with a minimum of 1 capsule which dosage is repeated at 3 day intervals until a satisfactory response is observed then a maintenance regimen is initiated with 1 capsule per 10 pounds of body weight, minimum of 1 capsule, every 3 days, or 7 days, or longer as required to maintain continued improvement or an asymptomatic condition.
- (3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.
- [40 FR 13838, Mar. 27, 1975, as amended at 52 FR 7832, Mar. 13, 1987; 52 FR 9756, Mar. 26, 1987]

§ 520.2123 Spectinomycin oral dosage forms.

§520.2123a Spectinomycin tablets.

- (a) Specifications. Each tablet contains spectinomycin dihydrochloride pentahydrate equivalent to 100 milligrams (mg) spectinomycin.
- (b) Sponsor. See No. 061623 in $\S 510.600(c)$ of this chapter.

- (c) Conditions of use in dogs—(1) Amount. Administer orally to provide 10 mg per pound (lb) of body weight twice daily. Dosage may be continued for 4 consecutive days.
- (2) Indications for use. For the treatment of infectious diarrhea and gastroenteritis caused by organisms susceptible to spectinomycin.
- (3) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[73 FR 6607, Feb. 5, 2008]

§520.2123b Spectinomycin powder.

- (a) Specifications. Each gram (g) of powder contains spectinomycin dihydrochloride pentahydrate equivalent to 0.5 g spectinomycin.
- (b) *Sponsor*. See No. 061623 in §510.600(c) of this chapter.
- (c) Related tolerances. See §556.600 of this chapter.
- (d) Conditions of use in chickens. It is administered in the drinking water of growing chickens as follows:
- (1) Indications for use and amounts—(i) For increased rate of weight gain and improved feed efficiency in broiler chickens, administer 0.5 g per gallon of water as the only source of drinking water for the first 3 days of life and for 1 day following each vaccination.
- (ii) As an aid in controlling infectious synovitis due to *Mycoplasma synoviae* in broiler chickens, administer 1 g per gallon of water as the only source of drinking water for the first 3 to 5 days of life.
- (iii) As an aid in the prevention or control of losses due to CRD associated with *M. gallisepticum* (PPLO) in growing chickens, administer 2 g per gallon of water as the only source of drinking water for the first 3 days of life and for 1 day following each vaccination.
- (2) *Limitations*. Do not administer to laying chickens. Do not administer within 5 days of slaughter.

[73 FR 6607, Feb. 5, 2008]

§520.2123c Spectinomycin solution.

(a) Specifications. Each milliliter of solution contains spectinomycin dihydrochloride pentahydrate equivalent to 50 milligrams (mg) spectinomycin.